REMARKS

Claims 28 and 30 are pending in this application. Claims 28 and 30 have been rejected. Claims 28 and 30 have been amended. No new matter has been added by this amendment. Reconsideration is respectfully requested.

I. Withdrawn Rejections

Applicants acknowledge the withdrawal of the rejection of claims 30-31 under 35 U.S.C. §101 and claim 29 under 35 U.S.C. §112, first paragraph.

II. Double Patenting

Claim 30 remains rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,587,288. It is suggested that the SarA is an analog of SarR protein that can serve to autoregulate sarA. The Examiner suggests that the composition of claim 30 need not evidence any specific biological structure or function, but must be identified by the screening method, the identification not requiring any specific activity, and therefore SarA serves the recited intended us of claim 30, that being a "pharmaceutical composition". Applicants respectfully disagree with this rejection.

It is respectfully pointed out that the screening method clearly sets forth in the preamble the identification of lead compounds which inhibit the expression of *sarA* in *Staphylococcus*. Moreover, a compound of the screening assay forms a heterodimer with the SarA protein and therefore could not, by definition, be SarA itself. However, in an earnest effort to clarify the nature of

the compounds identified by the screening method of claim 28, claim 30 has been amended to indicate that the compound is a SarR protein from *Staphylococcus aureus, S. epidermidis, S. haemolyticus,* or *S. saprophyticus* which inhibits the expression of *sarA*. In this regard, because the autoregulation of *sarA* by the SarA protein is via homodimer formation which activates protein expression, and the instant inhibitors are SarR proteins which form heterodimers with SarA thereby inhibiting *sarA* expression, this reference cannot be held to make obvious the instant invention. It is therefore respectfully requested that this rejection be reconsidered and withdrawn.

Claim 28 has been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 22 of co-pending Application No. 11/063,308. It is suggested that while the claims are not identical, they are not patentably distinct.

Applicants respectfully request that this rejection be held in abeyance until allowable subject matter has been identified in co-pending Application No. 11/063,308.

III. Objection to the Specification

The Examiner has maintained the objection to the specification because it contains embedded hyperlinks and/or other forms of browser-executable code. Specifically, the Examiner requires that the phrase www.tiger.org be removed from the specification at page 30. In Applicants response filed January 12, 2006, Applicants inadvertently referred to the objected text as beginning at page 24. Thus, Applicants submit herewith a replacement paragraph

beginning at page 30, line 8, reiterating previous amendments submitted in the response filed January 12, 2006. In light of this amendment, it is respectfully requested that this objection be withdrawn.

IV. Rejection of Claims under 35 U.S.C. §112

Claims 28 and 30 remain rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. It is the Examiner's position the SEQ ID NO:1 is not an amino acid sequence, but a nucleotide sequence, and the combination of claim limitations is not consistent with accepted nomenclature for what represents an amino acid sequence. The Examiner further suggests that the claimed method and composition do not utilize the sarR protein of Figure 11, but analogs thereof, the sequences and structures of which are not known. It is suggested that the claimed pharmaceutical compositions of claim 30, identified by the method of claim 28, from which claim 30 depends, lack written description. It is also suggested that the limitation of "compound identified" lacks antecedent basis because the method of claim 28 does not contain a method step of identifying.

Claim 30 also remains rejected under 35 U.S.C. §112, first paragraph, as lacking enablement. The Examiner suggests that while the disclosure is enabling for claims limited to SarR protein from *S. aureus*, *S. epidermidis*, *S. haemolyticus* and *S. saprophyticus*, on of skill in the art could not envision and produce SarR mutants without undue experimentation.

Applicants respectfully disagree with these rejections.

Out the outset, it is respectfully pointed out the SEQ ID NO:1 provides *both* amino acid and nucleotide sequences for SarR. As such, it would be clear to the skilled artisan upon looking at the sequences disclosed in SEQ ID NO:1, that Applicants are, as indicated in the claim, referring to the amino acid sequence of the SarR protein. However, in an earnest effort to facilitate the prosecution of this application, Applicants have amended claim 28 to recite the amino acid sequence of SarR set forth in SEQ ID NO:2. Support for this amendment is found at page 10, lines 9-10, which indicates that the SarR amino acid sequence is represented in SEQ ID NO:2. As such, Applicants have clearly set forth the reagents of the instant screening assay, namely a SarA protein and test agents (*i.e.*, one or more SarR analogs of a SarR protein having an amino acid sequence set forth in SEQ ID NO:2), as well as a defined end-point, namely the ability to form a heterodimer with the SarA protein, such that one of skill in the could readily carry out the instant assay and identify lead compounds that inhibit the expression of *sarA* in *Staphylococcus*.

Moreover, to provide antecedent basis for the compounds of claim 30, Applicants have amended this claim to recite that the pharmaceutical composition comprises an isolated and purified lead compound of claim 28. In so far as Applicants have clarified that the nature of the lead compound of the pharmaceutical composition of claim 30 is a SarR protein from *Staphylococcus aureus, S. epidermidis, S. haemolyticus,* or *S. saprophyticus* which inhibits *sarA* expression, it is respectfully believed that both written description and enablement requirements have been met for these compounds.

In light of the submitted claim amendments and accompanying remarks, it is respectfully requested that the rejection of claims 28 and 30 under 35 U.S.C. 112, first paragraph, be reconsidered and withdrawn.

V. Rejection of Claims under 35 U.S.C. §102

Claim 30 has been rejected under 35 U.S.C. §102(a) as being anticipated by Tegmark et al. (2000) on the grounds that there is no evidence of record to show that the SarR analog of Tegmark et al. would not function as an isolated and purified compound composition.

Claim 30 remains rejected under 35 U.S.C. §102(b) as being anticipated by Manna et al. (1998) in light of evidence provided by Manna et al. (2001) on the grounds that there is no evidence of record to show that the SarR analog of Manna et al. would not function as an isolated and purified compound composition.

Claim 30 remains rejected under 35 U.S.C. 102(e) as being anticipated by Hurlbert et al. (U.S. Patent no. 6,699,662) on the grounds that there is no evidence of record to show that the SarR analog of Hurlbert et al. would not function as an isolated and purified compound composition.

Claim 30 has also been rejected under 35 U.S.C. 102(e) as being anticipated by Doucette-Stamm et al. (U.S. Patent No. 6,380,370, SEQ ID NO:4993, filing date August 13, 1998). It is suggested that this reference teaches a composition which is an isolated and purified compound that is an analog of SEQ ID NO:2, or an analog encoded by SEQ ID NO:1, wherein the Staphyloccal polypeptide compound of Doucette-Stamm et al. shares 84.2% sequence identity with SEQ ID NO:2, and is therefore an analog of SarR

obtained from Staphylococcus with the recited intended use as a therapeutic.

MPEP 2131 states that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

The lead compound of claim 30 is a SarR protein from *Staphylococcus aureus, S. epidermidis, S. haemolyticus,* or *S. saprophyticus* which inhibits the expression of *sarA*. While Tegmark et al. teach an *S. aureus* P13 protein, Manna et al. teach an *S. aureus* 12 kD protein, Hurlbert et al. teach a mutant SarA protein, and Doucette-Stamm et al. teach a *S. epidermidis* protein with homology to SarR of *S. aureus*, these references do not teach or suggest the claimed SarR protein which inhibits the expression of *sarA*. Because these references fail to teach each and every element of that which is claimed, these references cannot be held to anticipate the present invention. It is therefore respectfully requested that these rejections be reconsidered and withdrawn.

VI. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly,

favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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